NATIONAL VACCINE ADVISORY COMMITTEE

Report of the Subcommittee on Improvement of Existing Vaccines (Dr. Wilfert)

Approved By The Full Committee September 13, 1989

Available vaccines have a remarkable record of efficacy and safety in the prevention of communicable diseases. Improvement of several of these vaccines has occurred when knowledge and technology allowed production of a more potent vaccine, a vaccine with fewer reactions, or a vaccine which was more effective. However, at the present time there is no established formal review mechanism for existing vaccines and the impetus to improvement has often been motivated primarily by potential financial benefit to a manufacturer. Recent developments in biotechnology and molecular biology should make improvements possible in virtually all vaccines.

It is essential to establish a mechanism for systematic review of available vaccines against infectious diseases on a continuing basis. The review should begin with the vaccines covered by the National Vaccine Injury Compensation Program. The review of these vaccines should be be completed by December of 1990. A schedule for the review will be developed and the review process will be coordinated by the National Vaccine Program. This review should be integrated with the review mandated by the National Vaccine Injury Compensation Program for improvement of existing vaccines should be integrated with the review mandated by the National Vaccine Compensation Program. Such a review will include the following aspects of current vaccines:

- 1. Efficacy, including duration of protection
- Adverse effects/safety
- 3. Immunogenicity
- 4. Vaccine improvements which would improve utilization and administration
- 5. Stability of vaccine and storage characteristics
- 6. Public and professional perception of these vaccines

The National Vaccine Program (NVP) will review these data at regular intervals and establish priorities for the improvement of existing vaccines. Recommendations for improvements encompass such diverse aspects as the technological improvements allowing cheaper more efficient production of antigens, development of different immunogens, e.g., purified polypeptides, vectors expressing recombinant antigens, or products causing fewer reactions.

The National Vaccine Advisory Committee will advise the Director of the National Vaccine Program about implementing the recommendations for improvement of existing vaccines. The Director of the National Vaccine Program will designate resources and persons to work toward the designated goals of vaccine improvement. Additional resources will be essential for the National Vaccine Program to complete the program of vaccine review, recommendations for improvement and implementation of those recommendations. The National Vaccine Advisory Committee will recommend that the Director of the National Vaccine Program secure the resources for carrying out these recommendations.